K052523

510(K) SUMMARY

SEP - 7 2006

1.1. ADMINISTRATIVE INFORMATION

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Contact Person:	Kimberly Briggs
	Senior Regulatory Affairs Specialist
Date:	February 14, 2006

1.2. PROXIS SYSTEM DEVICE INFORMATION

Name of Device:	Proxis System
Common Name:	Proximal Embolic Protection Device
Classification Name:	Device, coronary saphenous vein bypass graft, temporary, for embolization protection (870.1250)
Device Classification:	Class II
Product Code:	NFA

1.2.1. PREDICATE DEVICE INFORMATION

The Proxis System included in this 510k submission is for an expansion of indications to allow for use as an embolic protection system and for removal of soft thrombus.

This Proxis System is physically identical to the predicate Proxis System, which is market cleared for a Flow Control indication (K042117). The Proxis System is similar in function and intended use to market cleared predicate embolic protection systems: the FilterWire EX Embolic Protection System (K023691) & PercuSurge GuardWire Temporary Occlusion and Aspiration System (K013913). The Proxis System is also similar in function and intended use to existing predicate aspiration catheters used for removal of soft thrombus: the Pronto Catheter (K042937) & Export Catheter (K050139).

1.2.2. DEVICE DESCRIPTION

The Proxis Embolic Protection System is used in conjunction with other percutaneous transluminal coronary angioplasty devices (PTCA). It is compatible with 8F guide catheters. The Proxis System protects the patient from distal embolization by preventing antegrade flow of emboli released during a PTCA and then removing it from the vessel. The Proxis System consists of an Evacuation Sheath Catheter, Accessory Pack (contains an inflation system, evacuation syringe and double y-adaptor) and an optional additional accessory called the Proxis Infusion Catheter (packaged separately).

The Evacuation Sheath Catheter is loaded into the hemostasis valve and tracked down to the distal portion of the guide catheter. The Evacuation Sheath lines the inner lumen of the distal end of the guide catheter. When the sealing balloons are inflated, the proximal balloon seals against the guide catheter wall and the distal balloon seals against the blood vessel wall and the antegrade flow of the fluid in the target vessel is stopped. The stagnation of flow is accomplished before any devices touch or cross the lesion(s). This minimizes the distal release of embolic material.

Interventional devices are passed through the evacuation sheath to the treatment site and the procedure is performed in stagnant fluid. After the procedure, fluid and particles from the procedure are evacuated using the Evacuation Syringe. The Proxis Infusion Catheter may be used to augment the retrograde flow during the evacuation by infusing saline distal to the treatment site while simultaneously applying vacuum to evacuate fluid and particles from the treatment site.

1.2.3. INTENDED USE

The Proxis System is indicated for use as a proximal embolic protection system to prevent distal release of and to aspirate embolic material (thrombus/debris) in saphenous vein coronary bypass graft(s) (3.0 mm - 5.0 mm) during percutaneous transluminal coronary angioplasty and/or stenting procedures.

The Proxis System is also indicated to control the flow of fluids and aid in the removal of fresh, soft emboli and thrombi in the coronary and peripheral vasculature.

The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral, carotid or peripheral vasculature; native coronary arteries; or for treatment of patients with acute myocardial infarction.

1.2.4. TECHNOLOGICAL CHARACTERISTICS

The Proxis device is the same Proxis device that was cleared under the flow-control indication (K042117). It is identical in design, technological characteristics, manufacturing, testing and principles of operation. The only difference is an expansion of the indications for embolic protection and soft thrombus removal. The embolic protection expansion is supported by clinical data from the Proximal Trial that demonstrates substantial equivalence to previously cleared predicate devices that have similar indications, i.e. FilterWire EX Embolic Protection System (K023691) and PercuSurge GuardWire Temporary Occlusion and Aspiration System (K013913). The soft thrombus removal is supported by bench testing that demonstrates the Proxis device performs as well as predicate devices that have similar indications, i.e. Pronto (K042937) or Medtronic Export Catheter (K050139). In addition, the Proxis System provides a similar low pressure balloon occlusion; embolic protection and aspiration for retrieval of emboli similar to the other previously identified predicate devices. The primary difference in technologies to the predicate devices is that the Proxis System provides proximal occlusion vs. distal occlusion.

1.3. SUMMARY OF NON-CLINICAL TESTING

Non-clinical verification and validation of the Proxis System was performed through extensive in vitro bench testing, biocompatibility testing, and sterilization, shelf life testing and *in vivo* animal studies. Results of the testing demonstrated that the Proxis System design met all specifications and intended uses.

1.4. SUMMARY OF CLINICAL DATA

The Proximal Trial was performed to assess the safety and effectiveness of the Proxis System for embolic protection during percutaneous treatment of saphenous vein graft (SVG) stenosis. The study consisted of a test arm (Proxis Embolic Protection System) and a control arm (market cleared distal protection devices, FilterWire and GuardWire). Six-hundred (600) randomized patients, with 117 additional roll-in and 5 educational patients were enrolled in 68 investigational sites in Canada, Europe and the United States. Five-hundred ninety-four (594) randomized patients were included in the analysis. The following conclusions resulted from the study:

- For the intent-to treat population, the 30 day MACE rate is 9.2% in the Test arm and 10.0% in the Control arm, with an upper CI of 4%, which is well below the non-inferiority absolute delta of 7.0%, and below the relative delta of 5.5% (p value for non-inferiority 0.006).
- For the as-treated population, the Proxis 30 day MACE rate is 7.1% for protection with the Proxis System, and 11.7% for protection with the distal protection devices (FilterWire/GuardWire). The upper CI of the difference between the groups is 0.3%, again below both the non-inferiority absolute delta of 7.0% and the relative delta of 5.5% (non-interiority p value < 0.001).

1.5 CONCLUSION

In conclusion, the Proxis System included in this submission is substantially equivalent to the existing Proxis System, FilterWire Embolic Protection System, Guardwire Temporary Occlusion and Aspiration System, Pronto Catheter and the Export Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 7 2006

Ms. Kimberly Briggs
Senior Regulatory Affairs Specialist
St. Jude Medical
6550 Wedgwood Road North, Suite 150
Minneapolis, MN 55311

Re: K052523/S3
Trade/Device Name: Proxis System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NFA
Dated: August 28, 2006
Received: August 29, 2006

Dear Ms. Briggs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052523

Device Name: Proxis System

Indications for Use:

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Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochmer

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K052523